## **Essential #1: Your Recommendation**

- **1.** The positive impact of advice from a doctor to get cancer screening is well-documented.
- 2. The magnitude of a clinician's impact is considerable: State surveys have shown that 90 percent of people who reported a physician recommendation for CRC testing were screened vs. 17 percent of those who reported no provider recommendation, and 72 percent of those whose physician recommended a stool blood test completed it vs. 8 percent of those whose physician had not.
- 3. Every clinician has seen patients who should have received, but did not receive, cancer screening. A consistent and reliable recommendation will result if three other essential elements an office policy, a reminder system, an effective communication system are part of the practice.
- **4.** The positive effect of a doctor's advice is limited to those who have access to a doctor or a usual source of care. All patients need a usual source of care.
- 5. To prevent CRC and reduce mortality, the recommendation must include a referral for colonoscopy where any non-colonoscopy screening test is positive.

Barrier	Clarification and Resolution	
Outdated knowledge	<ul> <li>The digital rectal exam is not accepted practice.</li> <li>A single FOBT in the office is not evidence-based.</li> <li>A positive FOBT should not be dismissed as a likely false positive test. It should be followed up by a colonoscopy. Introduction, Essential #1, Guidelines.</li> </ul>	
Inconsistent guidelines	<ul> <li>Physicians often report concerns about inconsistencies in recommended guidelines.</li> <li>In fact, differences between guidelines are minimal.</li> <li>Risk stratification must be a priority. Introduction, Essential #2, Guidelines.</li> </ul>	
Guideline changes	<ul> <li>The digital rectal exam is no longer an accepted screening practice.</li> <li>As additional evidence becomes available, guideline elements, i.e. age to begin screening, the screening interval, the use of different modalities, also will change. Essential #2, Guidelines.</li> </ul>	
Screening overestimated	• Physicians frequently estimate higher screening rates than the actual rates. This may dissipate a sense of urgency about screening.  The Screening Practices of Primary Care Physicians.	
Confusion about goals	<ul> <li>The most common achievement of screening is the removal of an adenomatous polyp. Introduction.</li> </ul>	
Lack of confidence by doctors	<ul> <li>There is high-quality evidence for the efficacy of screening.</li> <li>Patient acceptance is better than some physicians may believe.</li> <li>Introduction, Essential #2.</li> </ul>	
Cost and reimbursement	<ul> <li>Cost of FOBT is low and colonoscopy cost is declining.</li> <li>Consult health departments where the uninsured cannot access complete diagnostic examinations.</li> <li>Discuss the barrier of copays and deductibles. Introduction.</li> </ul>	
Inadequate resources and reinforcement systems	<ul> <li>Nationwide, there are sufficient resources to screen the entire eligible population within one year with FOBT, plus colonoscopy for all positives. (See reference #38.)</li> <li>Communication strategies can raise efficiency.</li> <li>Office reminder and reinforcement systems are discussed in the section "Essential #3."</li> <li>Introduction, Essential #4, The Screening Practices of Primary Care Physicians.</li> </ul>	

Common Sense Colorectal Cancer Screening Recommendations at a Glance		
Risk Category	Age to Begin Screening	Recommendations
Average risk No risk factors No symptoms²	< Age 50 ≤ Age 50	No screening needed  Screen with any one of the following options:  Tests That Find Polyps  and Cancer  FS q 5 yrs*  CS q 10 yrs  DCBE q 5 yrs*  CTC q 5 yrs*  OR  Tests That Primarily  Find Cancer  gFOBT q 1 yr*,**  FIT q 1 yr*,**  sDNA***
Increased risk CRC or adenomatous polyp in a first-degree relative <sup>3</sup>	Age 40 or 10 years younger than the earliest diagnosis in the family, whichever comes first	Colonoscopy⁴
Highest risk Personal history for > 8 years of Crohn's disease or ulcerative colitis or a hereditary syndrome (HNPCC or, FAP, AFAP)	Any age	Needs specialty evaluation and colonoscopy

If the test is positive, a colonoscopy should be done.

The tests that are designed to find both early cancer and polyps are preferred if these tests are available and the patient is willing to have one of these more invasive tests.

- 1. Patients with a personal history of CRC or adenomatous polyp require a surveillance plan not screening.
- 2. Patients with symptoms merit an evaluation of their condition to precede screening.
- 3. The American Cancer Society and the US Multi-Society Task Force on Colorectal Cancer view a patient as being at average risk for the purpose of screening if only one first degree relative (FDR) > age 60 is affected. If the FDR is <50, or affected, also check for a history consistent with hereditary non-polyposis colorectal cancer. The criteria (Revised Amsterdam) for HNPCC are that there should be at least three relatives with HNPCC-associated cancers (colorectal, endometrium, small bowel, ureter, renal pelvis) and all of the following criteria must be met: 1) One should be a firstdegree relative of the other two. 2) At least two successive generations should be affected. 3) At least one cancer should be diagnosed before age 50. 4) Familial adenomatous polyposis should be excluded in the CRC case. 5) Tumors should be verified by pathological examination.
- 4. Colonoscopy for persons at increased risk is the recommendation of the American Cancer Society and the US Multi-Society Task Force on Colorectal Cancer. The US Multi-Society Task Force on Colorectal Cancer recommends repeat every five years, the American Cancer Society every five to10 years. The US Preventive Services Task Force (USPSTF) does not specifically recommend colonoscopy, but notes that colonoscopy is the most sensitive and specific modality.

Source: Adapted by the author from the guidelines of the Maryland State Cancer Programs (2005) and national guidelines.

<sup>\*\*</sup> The multiple stool take-home test should be used. One test done by the doctor in the office is not adequate for testing.

<sup>\*\*\*</sup> Interval uncertain.

TABLE 2 Guidelines for Screening for the Early Detection of Colorectal Cancer and Adenomas for Average-risk Women and Men Aged 50 Years and Older

The following options are acceptable choices for colorectal cancer screening in average-risk adults beginning at age 50 years. Since each of the following tests has inherent characteristics related to prevention potential, accuracy, costs, and potential harms, individuals should have an opportunity to make an informed decision when choosing one of the following options.

In the opinion of the guidelines development committee, colon cancer prevention should be the primary goal of colorectal cancer screening. Tests that are designed to detect both early cancer and adenomatous polyps should be encouraged if resources are available and patients are willing to undergo an invasive test.

#### Tests that Detect Adenomatous Polyps and Cancer

Test	Interval	Key Issues for Informed Decisions
FSIG with insertion to 40 cm or to splenic flexure	Every 5 years	Complete or partial bowel prep is required     Sedation usually is not used, so there may be some discomfort during the procedure     The protective effect of sigmoidoscopy is primarily limited to the portion of the colon examined     Patients should understand that positive findings on sigmoidoscopy usually result in a referral for colonoscopy
Colonoscopy	Every 10 years	<ul> <li>Complete bowel prep is required</li> <li>Conscious sedation is used in most centers; patients will miss a day of work and will need a chaperone for transportation from the facility</li> <li>Risks include perforation and bleeding, which are rare but potentially serious; most of the risk is associate with polypectomy</li> </ul>
DCBE	Every 5 years	Complete bowel prep is required     If patients have one or more polyps ≥6 mm, colonoscopy will be recommended; follow-up colonoscopy w require complete bowel prep     Risks of DCBE are low; rare cases of perforation have been reported
СТС	Every 5 years	Complete bowel prep is required     If patients have one or more polyps ≥6 mm, colonoscopy will be recommended; if same day colonoscopy is not available, a second complete bowel prep will be required before colonoscopy     Risks of CTC are low; rare cases of perforation have been reported     Extracolonic abnormalities may be identified on CTC that could require further evaluation
ests that Primarily Detec	t Cancer	
Test	Interval	Key Issues for Informed Decisions
aEORT with high concitivity	Annual	Depending on manufacturar's recommendations: 2 to 3 stead camples collected at home are needed to

Test	Interval	Key Issues for Informed Decisions
gFOBT with high sensitivity for cancer	Annual	Depending on manufacturer's recommendations, 2 to 3 stool samples collected at home are needed to complete testing; a single sample of stool gathered during a digital exam in the clinical setting is not an acceptable stool test and should not be done
FIT with high sensitivity for cancer	Annual	<ul> <li>Positive tests are associated with an increased risk of colon cancer and advanced neoplasia; colonoscopy should be recommended if the test results are positive</li> <li>If the test is negative, it should be repeated annually</li> <li>Patients should understand that one-time testing is likely to be ineffective</li> </ul>
sDNA with high sensitivity for cancer	Interval uncertain	<ul> <li>An adequate stool sample must be obtained and packaged with appropriate preservative agents for shipping to the laboratory</li> <li>The unit cost of the currently available test is significantly higher than other forms of stool testing</li> <li>If the test is positive, colonoscopy will be recommended</li> <li>If the test is negative, the appropriate interval for a repeat test is uncertain</li> </ul>

Abbreviations: FSIG, flexible sigmoidoscopy; DCBE, double-contrast barium enema; CTC, computed tomography colonography; gFOBT, guaiac-based fecal occult blood test; FIT, fecal immunochemical test; sDNA, stool DNA test.

TABLE 3 Guidelines for Screening and Surveillance for the Early Detection of Colorectal Adenomas and Cancer in Individuals at Increased Risk or at High Risk

Risk Category	Age to Begin	Recommendation	Comment
Increased Risk—Patients with Hi	story of Polyps at Prior Colonose	сору	
Patients with small rectal hyperplastic polyps <sup>26</sup>	_	Colonoscopy or other screening options at intervals recommended for average- risk individuals	An exception is patients with a hyperplastic polyposis syndrome. They are at increased risk for adenomas and colorectal cancer and need to be identified for more intensive follow up.
Patients with 1 or 2 small tubular adenomas with low- grade dysplasia <sup>26</sup>	5 to 10 years after the initial polypectomy	Colonoscopy	The precise timing within this interval should be based on other clinical factors (such as prior colonoscopy findings, family history and the preferences of the patient and judgment of the physician
Patients with 3 to 10 adenomas or 1 adenoma > 1 cm or any adenoma with villous features or high-grade dysplasia <sup>26</sup>	3 years after the initial polypectomy	Colonoscopy	Adenomas must have been completely removed. If the follow-up colonoscopy is normal or shows only 1 or 2 small, tubular adenomas with low-grade dysplasia, then the interval for the subsequent examination should be 5 years.
Patients with >10 adenomas on a single examination <sup>26</sup>	<3 years after the initial polypectomy	Colonoscopy	Consider the possibility of an underlying familial syndrome.
Patients with sessile adenomas that are removed piecemeal <sup>26</sup>	2 to 6 months to verify complete removal	Colonoscopy	Once complete removal has been established, subsequent surveillance needs to be individualized based on the endoscopist's judgment. Completeness of removal should be based on both endoscopic and pathologic assessments.
ncreased Risk—Patients with Co	olorectal Cancer		
Patients with colon and rectal cancer should undergo high-quality perioperative clearing <sup>25</sup>	3 to 6 months after cancer resection, if no unresectable metastases are found during surgery; alternatively, colonos- copy can be performed intra- operatively	Colonoscopy	In the case of nonobstructing tumors, this can be done by preoperative colonoscopy. In the case of obstructing colon cancers, CTC with intravenous contrast or DCBE can be used to detect neoplasms in the proximal colon.
Patients undergoing curative resection for colon or rectal cancer <sup>2</sup>	year after the resection (or 1 year following the performance of the colonoscopy that was performed to clear the colon of synchronous disease)	Colonoscopy	This colonoscopy at 1 year is in addition to the perioperative colonoscopy for synchronous tumors. If the examination performed at 1 year is normal, then the interval before the next subsequent examination should be 3 years. If that colonoscopi is normal, then the interval before the next subsequent examination should be 5 years. Following the examination at 1 year, the intervals before subsequent examinations may be shortened if there is evidence of HNPCC or if adenoma finding warrant earlier colonoscopy. Periodic examination of the rectur for the purpose of identifying local recurrence, usually performed at 3- to 6-month intervals for the first 2 or 3 years, may be considered after low-anterior resection of rectal cancer
ncreased Risk—Patients with a F		0.1	5
Either colorectal cancer or adenomatous polyps in a first- degree relative before age 60 years or in 2 or more first- degree relatives at any age <sup>24</sup>	Age 40 years or 10 years before the youngest case in the immediate family	Colonoscopy	Every 5 years
Either colorectal cancer or adenomatous polyps in a first- degree relative ≥age 60 years or in 2 second-degree relatives with colorectal cancer <sup>24</sup>	Age 40 years	Screening options at intervals recommended for average-risk individuals	Screening should begin at an earlier age, but individuals may choose to be screened with any recommended form of testing.

TABLE 3 (continued)

Risk Category	Age to Begin	Recommendation	Comment
High Risk			
Genetic diagnosis of FAP or suspected FAP without genetic testing evidence <sup>24</sup>	Aged 10 to 12 years	Annual FSIG to determine if the individual is expressing the genetic abnormality and counseling to consider genetic testing.	If the genetic test is positive, colectomy should be considered.
Genetic or clinical diagnosis of HNPCC or individuals at increased risk of HNPCC <sup>24</sup>	Aged 20 to 25 years or 10 years before the youngest case in the immediate family	Colonoscopy every 1 to 2 years and counseling to consider genetic testing	Genetic testing for HNPCC should be offered to first-degree relatives of persons with a known inherited MMR gene mutation. It should also be offered when the family mutation is not already known, but 1 of the first 3 of the modified Bethesda Criteria is present.
Inflammatory bowel disease, 24 chronic ulcerative colitis, and Crohn's colitis	Cancer risk begins to be significant 8 years after the onset of pancolitis or 12 to 15 years after the onset of left- sided colitis	Colonoscopy with biopsies for dysplasia	Every 1 to 2 years; these patients are best referred to a center with experience in the surveillance and management of inflammatory bowel disease

Abbreviations: FSIG, flexible sigmoidoscopy; DCBE, double-contrast barium enema; CTC, computed tomographic colonography; FAP, familial adenomatous polyposis; HNPCC, hereditary nonpolyposis colon cancer; MMR, mismatch repair.

# U.S. Preventive Services Task Force Summary of Colorectal Cancer Screening Recommendations

The U.S. Preventive Services Task Force (USPSTF) strongly recommends that clinicians screen men and women 50 years of age or older for colorectal cancer. There are insufficient data to determine which strategy is best in terms of the balance of benefits and potential harms or cost-effectiveness. Studies reviewed by the USPSTF indicate that colorectal cancer screening is likely to be cost-effective (less than \$30,000 per additional year of life gained) regardless of the strategy chosen.

Test	Interval (Beginning at age 50)	Comment
Fecal Occult Blood Test (FOBT) and Flexible Sigmoidoscopy	FOBT every year plus flexible sigmoidoscopy at an unspecified interval	The combination of FOBT and sigmoidoscopy may detect more cancers and more large polyps than either test alone, but the additional benefits and potential harms of combining the two tests are uncertain. In general, FOBT should precede sigmoidoscopy because a positive test result is an indication for colonoscopy, obviating the need for sigmoidoscopy.
Flexible Sigmoidoscopy	Unspecified interval	Although sigmoidoscopy can only visualize the lower half of the colon, it has been estimated to identify 80 percent of all patients with significant findings in the colon, because findings on sigmoidoscopy will trigger examination of the entire colon.
Fecal Occult Blood Test (FOBT)	Every year	Proven methods of FOBT screening use guaiac-based test cards prepared at home by patients from three consecutive stool samples and forwarded to the clinician. Whether patients need to restrict their diet and avoid certain medications is not established. Rehydration of the specimens before testing increases the sensitivity of FOBT but substantially increases the number of false-positive test results.
Colonoscopy	Unspecified interval	The USPSTF did not find direct evidence that screening colonoscopy is effective in reducing colorectal cancer mortality. Efficacy of colonoscopy is supported by its integral role in trials of FOBT, extrapolation from sigmoidoscopy studies, limited case-control evidence, and the ability of colonoscopy to inspect the proximal colon.
Double- Contrast Barium Enema (DCBE)	Unspecified interval	Double-contrast barium enema offers an alternative means of whole-bowel examination, but it is less sensitive than colonoscopy, and there is no direct evidence that it is effective in reducing mortality rates.

SOURCE: U.S. Preventive Services Task Force, 2002.

### **2008 Colorectal Cancer Screening Guidelines**

An Integrated Summary for Healthcare Professionals

Screening guidelines for colorectal cancer are similar among organizations. This summary is compiled by Barbara Lloyd MD in conjunction with the Comprehensive Cancer Control Program of the Montana Department of Health and Human Services. It integrates and summarizes recommendations from six national organizations.<sup>1</sup>

Beginning at age 50, both men and women at <u>average risk</u> for developing colorectal cancer (CRC) should use one of the screening tests below. An informed decision-making discussion between individuals and their healthcare provider determines which test is best for them. The best test is the one completed!

Detect Adenomatous Polyps and Cancer	Primarily Detect Cancer
Flexible sigmoidoscopy <sup>2</sup> (FSIG) every 5 yrs* or	Annual gFOBT <sup>2</sup> with hi sensitivity for cancer*,** or
Colonoscopy <sup>2,3</sup> every 10 yrs or	Annual FIT <sup>2</sup> with hi sensitivity for cancer*,** or
Double contrast barium enema (DCBE) every 5 yrs* or	sDNA with hi sensitivity for cancer*, (interval uncertain)
CT colonography (CTC) every 5 yrs*	
* Colonoscopy should be done if test results are positive	

### U.S. Preventive Services Task Force (USPSTF) 2008<sup>4</sup>:

- Recommended modalities = high-sensitivity FOBT, sigmoidoscopy with interval FOBT, or colonoscopy
- Recommend screening adults age 50 to 75 yrs; against routine screening 75-85 yrs (may be considerations supporting screening); against screening adults older than age 85 yrs
- Insufficient evidence to recommend for or against CTC and stool DNA (sDNA)

Five Organizations' Joint Guideline 2008<sup>5</sup>: Group tests into 2 categories: 1) Primarily Detect Cancer and 2) Detect Cancer and Polyps

- Strong preference for modalities that directly inspect colon: colonoscopy, FSIG, DCBE, or CTC
- Stool tests should be offered to those who cannot or will not have direct inspection: gFOBT, FIT, sDNA
- Recommend providers offer "Options" to increase screening rates & overcome barriers
- Sensitivity Threshold established for stool tests: should detect a > 50% of cancers in asymptomatic populations (currently recognized qualifying brands: gFOBT = Hemoccult SENSA,™ not Hemoccult II;™ FIT = Magstream 1000,™ Hemoccult ICT,™ or Insure™)<sup>‡</sup>
- Eliminated combined FOBT every yr in combination with FSIG every 5 yr. Either test performed according to guidelines is adequate alone
- Single office digital rectal exam with gFOBT on stool found is NOT recommended as screening
- Positive stool test should be followed up with colonoscopy, NOT a repeat stool test
- 2 New tests recommended for CRC screening = sDNA & CT Colonography

American Academy of Family Physicians (AAFP) endorses USPSTF recommendations.<sup>6</sup>

American College of Obstetricians and Gynecologists (ACOG) 2007<sup>7</sup>: recommend colonoscopy as the preferred method for colorectal cancer screening for both average-risk and high-risk women but still recommend discussing the advantages and limitations of the other screening options.

Individuals with above-average risk from any of the following risk factors should be counseled about starting CRC screening with colonoscopy earlier and/or being screened more often:

- personal history of colorectal cancer or adenomatous polyps
- personal history of chronic inflammatory bowel disease (Crohns disease or ulcerative colitis)
- strong family history of colorectal cancer or polyps (cancer or polyps in a first-degree relative [parent, sibling, or child] younger than 60 or in 2 or more first-degree relatives of any age)
- known family history of hereditary colorectal cancer syndromes such as familial adenomatous polyposis (FAP) or hereditary non-polyposis colon cancer (HNPCC)

<sup>\*\*</sup> For CRC screening with gFOBT or FIT, high sensitivity take-home multiple sample card is used (not the single in-office test)

<sup>&</sup>lt;sup>‡</sup> Listing brands here does not imply endorsement by the Montana Department of Health and Human Services.

Pros and Cons of CRC Screening Tests <sup>8</sup>			
Test	Pros	Cons	
Flexible Sigmoidoscopy Sensitivity for CRC = 60-70% \$150 - \$300 <sup>9</sup>	Fairly quick and safe Minimal bowel preparation Sedation usually not used Does not require a specialist Done every 5 years	Views only about a third of the colon Can't remove all polyps May be some discomfort Done in a doctor's office, clinic, or hospital Very small risk of bleeding, infection, bowel tear Colonoscopy needed if abnormal	
Colonoscopy Sensitivity for CRC = 95% \$800 - \$16009	Can usually view entire colon Can biopsy and remove polyps Done every 10 years Can diagnose other diseases	Can miss small polyps Full bowel preparation needed More expensive on a one-time basis Sedation of some kind is usually needed May require a missed day of work & a chauffer Small risk of bleeding, tears, or infection	
Double Contrast Barium Enema (DCBE) Sensitivity for CRC = 85-97% \$250 - \$5009	Can usually view entire colon Relatively safe Done every 5 years No sedation needed	Can miss small polyps Full bowel preparation needed Some false positive test results Cannot remove polyps during testing Colonoscopy needed if abnormal	
CT Colonography (Virtual Colonoscopy) Sensitivity for CRC = unknown large adenomas= 96% \$400 - \$800 10	Fairly quick and safe Can usually view entire colon Done every 5 years No sedation needed	Can miss small polyps Full bowel preparation needed Some false positive test results Cannot remove polyps during testing Colonoscopy needed if abnormal Still fairly new - may be insurance issues	
Fecal Occult Blood Test (FOBT) Sensitivity for CRC = varies (64% for Hemoccult SENSA™‡) \$10 - \$259	No direct risk to the colon No bowel preparation Sampling done at home Inexpensive	May miss many polyps and some cancers May produce false-positive test results May have pre-test dietary limitations Should be done annually Organized system needed for follow-up Colonoscopy needed if abnormal	
Fecal Immunochemical Test (FIT) Sensitivity for CRC = varies (66% for Magstream FIT™‡) \$28 <sup>11</sup>	No direct risk to the colon No bowel preparation Sampling done at home No pre-test dietary restrictions Fairly inexpensive	May miss many polyps and some cancers May produce false-positive test results Should be done annually Colonoscopy needed if abnormal	
Stool DNA Test Sensitivity for CRC = 70% (for version 1.1 <sup>™‡</sup> ) \$350 12	No direct risk to the colon No bowel preparation No pre-test dietary restrictions Sampling done at home	May miss many polyps and some cancers May produce false-positive test results More expensive than other stool tests Still fairly new - may be insurance issues Not clear how often it should be done Colonoscopy needed if abnormal	

<sup>1</sup> USPSTF, the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer (American Gastroenterological Association, American College of Gastroenterology, American Society of Gastrointestinal Endoscopists), the American College of Radiology, AAFP, & ACOG

2 Tests recommended by U.S. Preventive Services Task Force

6 American Academy of Family Physicians: <a href="http://www.aafp.org/online/en/home/clinical/exam/a-e.html">http://www.aafp.org/online/en/home/clinical/exam/a-e.html</a>

7 American College of Obstetricians and Gynecologists (ACOG) http://www.acog.org/from\_home/publications/press\_releases/nr10-26-07-2.cfm

8 Modified from American Cancer Society: <a href="http://www.cancer.org">http://www.cancer.org</a>

Cost estimates are the typical range of rates and may not include costs of related services: Screen for Life, Colorectal Cancer Facts on Screening, 2006 <a href="http://www.cdc.gov/cancer/colorectal/pdf/fs-patient.pdf">http://www.cdc.gov/cancer/colorectal/pdf/fs-patient.pdf</a>

10 http://www.scandirectory.com/content/virtual\_colonoscapy.asp

- 11 <a href="http://www.cms.hhs.gov/mcd/viewtechassess.asp?where=index&tid=20">http://www.cms.hhs.gov/mcd/viewtechassess.asp?where=index&tid=20</a>
- 12 http://www.cms.hhs.gov/determinationprocess/downloads/id52TA.pdf

‡ Listing brands here does not imply endorsement by the Montana Department of Health and Human Services.

<sup>3</sup> Test recommended by the American College of Obstetricians and Gynecologists

<sup>4</sup> U.S. Preventive Services Task Force (USPSTF) <a href="http://www.ahrq.gov/clinic/uspstf/uspscolo.htm">http://www.ahrq.gov/clinic/uspstf/uspscolo.htm</a>
5 Screening and Surveillance for the Early Detection of Colorectal Cancer and Adenomatous Polyps, 2008: A Joint Guideline http://caonline.amcancersoc.org/cgi